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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,462	05/08/2001	Edwin Mellor Southern	SHW-004US	5936

7590

10/23/2002

Anthony A Laurentano
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28 State Street
Boston, MA 02109

EXAMINER

RILEY, JEZIA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 10/23/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,462

Applicant(s) *

SOUTHERN ET AL.

Examiner

Jezia Riley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 24-41, 44-58, 60, 61, 63-65 and 70-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 42, 43, 59, 62, and 66-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 9 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 12-23, 67, 68, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Dower et al. (WO 93/06121).

Dower discloses a method for synthesizing libraries of random oligomers. The random oligomers are synthesized on solid supports, or particles, but may be cleaved from these supports to provide a soluble library. The oligomers are composed of a sequence of monomers. Each oligomer sequence in the library is unique. The solid supports may be composed of a single particle, or two or more linked particles. A further embodiment relates to the use of an identifier tag to identify the sequence of monomers in the oligomer. The identifier tag, which may be attached directly to the oligomer with or without an accompanying particle, to a linker attached to the oligomer, to the solid support upon which the oligomer is synthesized, or to a second particle attached to the oligomer-carrying particle, may be any recognizable feature that in some

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way carries the required information, and that is decipherable at the level of one or few solid supports. The solid supports may be joined to the oligomers and the identifier tag by means of one or more linker molecules. The identifier tag is an oligonucleotide, or a set of light-addressable compounds, such as fluorescent or phosphorescent compounds that can be photo leached, which compounds are incorporated into the beads or particles on which the oligomers of the oligomer library are synthesized. Such compounds are widely known in the art (Pages 4-7, Pages 22-23, Example I),. Figure 3 describes one method of bead functionalization. Figure 4 is a schematic representation of one example of an oligonucleotide tag. Figure 5 illustrates nucleoside phosphoramidites derivatized with photolabile groups. One can readily produce up to 10^{12} different oligomers (pages 11-12).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-23, 42, 43, 59, 62, and 66-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dower et al. (WO 93/06121) in view of Koster (6,074,823) in view Van Ness (WO 97/27331).

Dower discloses a method for synthesizing libraries of random oligomers. The random oligomers are synthesized on solid supports, or particles, but may be cleaved from these supports to provide a soluble library. The oligomers are composed of a sequence of monomers. Each oligomer sequence in the library is unique. The solid supports may be composed of a single particle, or two or more linked particles. A further embodiment relates to the use of an identifier tag to identify the sequence of monomers in the oligomer. The identifier tag, which may be attached directly to the oligomer with or without an accompanying particle, to a linker attached to the oligomer, to the solid support upon which the oligomer is synthesized, or to a second particle attached to the oligomer-carrying particle, may be any recognizable feature that in some way carries the required information, and that is decipherable at the level of one or few solid supports. The solid supports may be joined to the oligomers and the identifier tag by means of one or more linker molecules. The identifier tag an oligonucleotide, or a set of light-addressable compounds, such as fluorescent or phosphorescent compounds that can be photo leached, which compounds are incorporated into the beads or

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particles on which the oligomers of the oligomer library are synthesized. Such compounds are widely known in the art (Pages 4-7, Pages 22-23, Example I),. Figure 3 describes one method of bead functionalization. Figure 4 is a schematic representation of one example of an oligonucleotide tag. Figure 5 illustrates nucleoside phosphoramidites derivatized with photolabile groups. One can readily produced up to 10^{12} different oligomers (pages 11-12).

Koster discloses that in general, when it is the released nucleotide (or ribonucleotide) which is mass-modified, the modification should take as few steps as possible and be relatively efficient. For example, reactions used in adding base protecting groups for oligonucleotide synthesis can also be used to modify the released nucleotide just prior to mass spectrometric analysis. For instance, the amino function of adenine, guanine or cytosine can be modified by acylation. The amino acyl function can be, by way of illustration, an acetyl, benzoyl, isobutyryl or anisoyl group. Benzoylchloride, in the presence of pyridine, can acylate the adenine amino group, as well as the deoxyribose (or ribose) hydroxyl groups. As the glycosidic linkage is more susceptible to hydrolysis, the sugar moiety can be selectively deacylated if the acyl reaction was not efficient at those sites (i.e. heterogeneity in molecular weight arising from incomplete acylation of the sugar). The sugar moiety itself can be the target of the mass-modifying chemistry. For example, the sugar moieties can be acylated, tritylated, monomethoxytritylated, etc. Other chemistries for mass-modifying the released nucleotides (or ribonucleotides) will be apparent to those skilled in the art.

Van Ness discloses methods and compositions for determining the sequence of nucleic acid molecules. The methods permit the determination of multiple nucleic acid sequences simultaneously. The compounds are used as tags to generate tagged nucleic acid fragments which are complementary to a selected target nucleic acid molecule. Each tag is correlative with a particular nucleotide and is detectable by mass spectrometry. Following separation of the tagged fragments by sequential length, the tags are cleaved from the tagged fragments. The tags are detected by mass spectrometry and the sequence of the nucleic acid molecule is determined.

Therefore it would have been obvious at the time the invention was made to one of ordinary skill in the art to use mass tag as taught by Van Ness for the method of Dower. The said tag possesses several attributes. It is capable of being distinguished from all other tags. It is capable of being detected when present at 10^{-22} to 10^{-6} mole. It is chemically stable toward all manipulations to which it is subjected; etc. It would possess properties which enhance the sensitivity and specificity of detection (Van Ness pages 26-27).

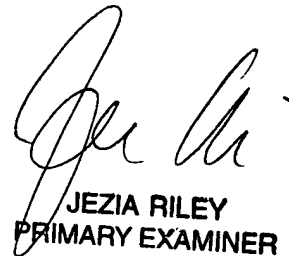
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:30AM - 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

October 18, 2002



JEZIA RILEY
PRIMARY EXAMINER